United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

30876-30900

DRUGS

[Approved by the Acting Secretary of Agriculture, Washington, D. C., November 22, 1939]

80876. Adulteration and misbranding of ether U. S. P. 10 (ethyl oxide U. S. P. XI). U. S. v. 15 Cans of "Ether U. S. P. 10 * * * (Ethyl oxide U. S. P. XI)," and 9 other seizure actions against the same product. Default decrees of condemnation and destruction. (F. & D. Nos. 45238, 45239, 45266, 45288, 45289, 45325, 45329, 45418, 45420, 45421, 45445. Sample Nos. 5469-D, 45265-D, 52307-D, 52512-D, 53655-D, 55656-D, 57642-D, 59029-D, 62836-D, 62837-D, 69031-D.)

This product had been shipped in interstate commerce and remained unsold and in the original packages. At the time of examination, samples consisting of 10 cans taken from each of 10 shipments, showed the presence in the product of peroxide in 4, 10, 4, 2, 3, 7, 2, 7, 8, and 3 cans, respectively; and a sample, consisting of 5 cans from another shipment, showed the presence of peroxide in all 5 cans.

peroxide in all 5 cans.

Between April 27 and June 3, 1939, the United States attorneys for the Southern District of Florida, the Western District of New York, the Southern District of California, the Eastern District of Michigan, District of Massachusetts, Southern District of Ohio, and the Northern District of Texas, acting upon reports by the Secretary of Agriculture, filed in their respective district courts libels praying seizure and condemnation of 451 cans of ether (ethyl oxide) in various lots at Tampa, Fla., Rochester, N. Y., Los Angeles, Calif., Detroit, Mich., Rutland, Mass., Dayton, Ohio, Buffalo, N. Y., and Dallas, Tex.: alleging that the article had been shipped in interstate commerce within the period from on or about November 19, 1938, to on or about May 4, 1939, by Merck & Co., Inc., in various shipments from New York, N. Y., Rahway, N. J., Newark, N. J., and St. Louis, Mo.; and charging adulteration and misbranding in violation of the Food and Drugs Act.

The article in all cases, except one shipment to Buffalo, N. Y., was alleged to be adulterated in that it was sold under names recognized in the United States Pharmacopoeia, i. e., "Ether" and "Ethyl Oxide," but differed from the standard of strength, quality, and purity as determined by the tests laid down in the pharmacopoeia, and its own standard of strength, quality, and purity was not stated on the label. In all cases it was alleged to be adulterated in that its strength and purity fell below the professed standard and quality under which it was sold, namely, "Ether U. S. P. 10," since it did not conform to the specifications of the said pharmacopoeia for ether because it contained peroxide.

The article was alleged to be misbranded in that the statement on the label, "Ether U. S. P. 10 * * * (Ethyl Oxide U. S. P. XI)," with respect to all lots but one and the statement "Ether U. S. P. 10" with respect to one lot were false and misleading since it did not conform to the specifications of the tenth revision of the United States Pharmacopoeia for ether and all lots, with one exception, failed to conform to the specifications of the eleventh revision of the pharmacopoeia for ethyl oxide.

Between May 23 and September 8, 1939, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed with the exception of one lot which was ordered turned over to the Food and Drug Administration.

M. L. Wilson, Acting Secretary of Agriculture.